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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/601,692	06/24/2003	Makiko Fliss	001107.00357	7618

22907 7590 08/14/2006

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EXAMINER

FREDMAN, JEFFREY NORMAN

ART UNIT PAPER NUMBER

1637

DATE MAILED: 08/14/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/601,692	FLISS ET AL.	
	Examiner	Art Unit	
	Jeffrey Fredman	1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 July 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 39,40 and 118-126 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 39,40 and 118-126 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>06/24/03</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of the oligonucleotides which comprise a deletion of C mutation at position 302 in the reply filed on July 5, 2006 is acknowledged.

Specification

2. The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

For example, at page 12, line 6, there is a hyperlink.

Claim Rejections - 35 USC § 112

3. Claims 39, 40 and 118-126 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

These claims are indefinite because the term "ΔC mutation at nucleotide 302" is indefinite in the context of the sequence submitted as SEQ ID NO: 1. The only sequence long enough to have a deletion at position 302 is SEQ ID NO: 1. However, the nucleotide at position 302 of SEQ ID NO: 1 is an "A". That "A" is followed by a run of 7 "C" bases at positions 303-309. That "A" also is preceded by a "C" at position 299. It is indefinite which "C" is intended to be deleted. If the run of 7 "C" bases is meant, it is unclear if the deletion is intended to encompass a single "C" base or multiple "C" bases. For purposes of the prior art, the claims will be interpreted as meaning one of two different possibilities. Either SEQ ID NO: 1 already has the deletion of the "C" base or

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there is a deletion of a C subsequent to position 302, resulting in a run of 6 "C" bases in the place of the seven "C" bases shown in SEQ ID NO: 1.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 39, 40 and 118-126 are rejected under 35 U.S.C. 102(b) as being anticipated by Genbank Accession No. V00662 (1992).

This rejection relies upon the interpretation that SEQ ID NO: 1 already has the deletion of the "C" base. The run of 7 C bases is underlined. The query is Genbank Accession No. V00662 and here the Sbjct is SEQ ID NO: 1.

Genbank Accession No V00662 teaches a sequence which perfectly matches the Sequence of SEQ ID NO: 1.

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Query  241  ACAATTGAATGTCTGCACAGCCACTTTCCACACAGACATCATAACAAAAAATTTCCACCA  300
          |||
Sbjct  241  ACAATTGAATGTCTGCACAGCCACTTTCCACACAGACATCATAACAAAAAATTTCCACCA  300

Query  301  AACCCCCCTCCCCGCTTCTGGCCACAGCACTTAAACACATCTCTGCCAAACCCCAAAA  360
          |||
Sbjct  301  AACCCCCCTCCCCGCTTCTGGCCACAGCACTTAAACACATCTCTGCCAAACCCCAAAA  360

Query  361  ACAAAGAACCCTAACACCAGCCTAACCCAGATTTCAAATTTTATCTTTTGGCGGTATGCAC  420
          |||
Sbjct  361  ACAAAGAACCCTAACACCAGCCTAACCCAGATTTCAAATTTTATCTTTTGGCGGTATGCAC
420.

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With regard to claims 29, 40 and 118-126, the sequence of Genbank Accession No. V00662 comprises more than 30 contiguous nucleotides of the mitochondrial genome identical to SEQ ID NO: 1 as shown in the alignment above.

6. Claims 39, 40 and 118-126 are rejected under 35 U.S.C. 102(b) as being anticipated by Genbank Accession No. U25391 (1995).

This rejection relies upon the interpretation that SEQ ID NO: 1 lacks the deletion of the "C" base, and therefore only a run of 6 C bases is present. The run of 6 C bases is underlined. The query is Genbank Accession No. U25391 and the Sbjct is SEQ ID NO: 1.

Genbank Accession No U25391 teaches a sequence which has a deletion of a C relative to SEQ ID NO: 1 after position 302, and comprises 52 contiguous nucleotides identical to the delta 302 C deletion of SEQ ID NO: 1 as shown in the alignment below.

Query		CTTTCCACACA	599
Sbjct		CTTTCCACACA	274
Query	600	GACATCATAACAAAAAATTTCCACCAA	<u>CCCCCTCCCC</u>
Sbjct	275	GACATCATAACAAAAAATTTCCACCAA	ACCCCCCTCCCC

With regard to claims 29, 40 and 118-126, the sequence of Genbank Accession No. U25391 comprises more than 30 contiguous nucleotides of the mitochondrial genome identical to the delta 302 C deletion of SEQ ID NO: 1 as shown in the alignment above

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7. Claims 39 and 40 are rejected under 35 U.S.C. 102(b) as being anticipated by Brennan et al (U.S. Patent 5,474,796).

Brennan teaches the formation of an array which comprises every single 10-mer (see column 9, lines 53-55). This complete set of 10-mers necessarily and inherently comprises all of the 10-mers of claims 39 and 40 and would inherently comprise all the 10 mers which are capable of hybridizing to the selected sequences with the required specificities.


Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey Fredman whose telephone number is (571)272-0742. The examiner can normally be reached on 6:30-3:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (571)272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


Jeffrey Fredman
Primary Examiner
Art Unit 1637

7/18/01